Main Participant Information Sheet & Consent Form

Interventional Study

Life Clinical Research

Title	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Once Weekly Eloralintide in Adult Participants with Obesity or Overweight, without Type 2 Diabetes (ENLIGHTEN-1)
Short Title	ENLIGHTEN-1
Protocol Number	J3R-MC-YDAG
Project Sponsor	Eli Lilly and Company
Principal Investigator	Dr. Cameron Booth
Location	33 Thorn Street, Ipswich QLD 4305

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research study. This is because you have obesity or overweight without type 2 diabetes (T2D). The research project is testing a potential new treatment for your condition. The new treatment is called eloralintide.

This Participant Information Sheet and Consent Form tells you about the study. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the study.

Please read this information carefully. **Ask as many questions as possible about anything that you don't understand or want to know more about.** Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this study is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2. What is the purpose of this research?

Medications, drugs, and devices have to be approved for use by the Australian Federal Government Therapeutics Goods Administration (TGA). Eloralintide is not approved for the treatment of obesity or overweight without T2D in Australia and therefore it is an experimental treatment in this study. This means that it must be tested to see if it is an effective treatment for obesity or overweight without T2D.

The purpose of this study is to learn more about eloralintide for the treatment of obesity or overweight without T2D. The study aims to learn:

- Whether it can help reduce weight in participants with overweight or obesity without type 2 diabetes (T2D).
- Whether it works better than a placebo (a placebo is an inactive or “pretend” study drug).
- What are the possible side effects.

The study is being conducted by Eli Lilly and Company and sponsored in Australia by Eli Lilly Australia Pty Ltd.

3. What does participation in this research involve?

Throughout the Study

Some of the activities might happen at the doctor's office, at your home, or at other places, depending on the study and local rules.

The study doctor will explain the study to you, including:

- which treatments you can still use,
- how the study will be done and what you’ll need to do,
- and will answer any questions you have.

The study happens in periods. The activities may be a little different in each period, described in the sections below.

During the study, the study doctor will need to take a small amount of blood from you for testing and monitoring purposes. It is usually a few tubes of blood. This is similar to what is taken during a regular visit to your doctor. The total amount of blood that will be taken from you throughout the study will be approximately 486 mL (or about 32 tablespoons).

You will use a device to do some study activities. The device will be your own device, or one provided to you by the sponsor.

This study has 3 periods:

- **Screening Period:** Up to 5 weeks
- **Treatment Period:** Up to 64 weeks for participants without prediabetes and 168 weeks for participants with prediabetes.
- **Follow-Up Period:** Up to 6 weeks for participants without prediabetes and 23 weeks for participants with prediabetes.

Screening Period

Before any study-related procedures are done, the study doctor will explain the study to you and you will have time to read this Participant Information Sheet and Consent Form and ask any questions you may have. The study staff will review this document with you and will help answer any questions you may have now and during the study. If you agree to participate in the study you will need to sign and date this consent form. You will be given a copy of the signed Participant Information Sheet and Consent Form to keep, and the original copy will be put in your medical record.

The first part of this study is the Screening Period. It lasts about 5 weeks depending on your personal health care situation. This period will help figure out whether you can continue to the next part of the study.

During this time, you will have some tests and activities, including:

- Questions about your medical, surgical and family history, including medicines, vitamins, and herbal supplements you take and reported substance use
- Vital signs like blood pressure and heart rate
- Height, weight, and physical examination
- Blood draws and urine collection for laboratory tests
- Electrocardiogram (ECG), a test that measures the electrical activity of your heart
- Dual-energy X-ray absorptiometry (DXA) scan, an imaging test that measures your body composition, such as body fat and muscle mass
- Receive an electronic diary and instructions on how to use it
- Questionnaires related to the study
- Oral glucose tolerance test (OGTT), a test that helps the study doctor understand how well your body digests sugar. This test will be required only if you have prediabetes.

During this time, you can expect about 2 blood draws, 1 DXA scan, and about 1 ECG, but you might need to have more.

You may be asked if you want to go through another round of screening procedures if you don’t meet the screening criteria the first time.

If you are eligible for the study at the end of the Screening Period, you will enter the Treatment Period. If the study doctor decides that you are not eligible to take part in this study, they will discuss other treatment options for your condition with you.

Treatment Period

This period of the study lasts for about:

- 64 weeks for participants without prediabetes
- 168 weeks for participants with prediabetes.

This is when you get either eloralintide or placebo to compare how well they work. We refer to these all together as “study drug.”

Neither you nor your study doctor will know which study drug you are getting. The likelihood that you will receive the drug being studied will depend on how the study is set up and is determined by chance.

In this period, you will have a

- 22.2% chances of receiving placebo and
- 77.8% chance of receiving the eloralintide

During this time:

- You will take study drug for about 64 to 168 weeks by an injection under your skin.
    - You may be asked to fast for some study visits.
    - Your dose will gradually be increased about every 4 weeks during the first 12 weeks until you get to the full regular dose.
- You will have some tests/activities including:
    - Review of the medicines you take, receive lifestyle counselling, and maintain nutrition and physical activity log
    - Questions about history of substance use
    - Maintain the electronic diary
    - Weight, waist circumference, and physical examination
    - Vital signs like blood pressure and heart rate
    - Blood draws and urine collection for laboratory tests
    - ECG
    - DXA
    - Questionnaires related to the study
    - OGTT (only in participants with prediabetes)

For participants without prediabetes (64 weeks):

During this time, you can expect about 11 blood draws, 4 ECGs, and about 2 DXA scans, but you might need to have more. Ask the study doctor if you want to know more.

For participants with prediabetes (168 weeks):

An additional 9 blood draws, 5 ECGs, and 2 DXA scans might be needed between Week 64 and Week 168.

Each Treatment Period visit may be different in length depending on what tests will be done, but each visit is expected to take around 4 hours. Your study doctor will explain what you have to do and which tests you will have during the study.

Follow-Up Period

After you have finished with the treatment period and are no longer receiving study drug or you stop study drug, the study doctor will continue to check on your health. This is called the Follow-up Period, and it lasts for about 6 weeks for participants without prediabetes and 23 weeks for participants with prediabetes.

During this time:

- You will no longer receive study drug.
- You will have some tests/activities including:
    - Weight, waist circumference

- Vital signs like blood pressure and heart rate
- Blood draws for laboratory tests and urine collection
- Questionnaires related to the study

You can expect about 1 blood draw and 1 ECG during the follow-up period, but you might need to have more. Ask the study doctor if you want to know more.

This study will take about 75 weeks in participants without prediabetes and 196 weeks in participants with prediabetes.

What are the costs associated with joining the study?

You will receive the study drug, treatments, and procedures that are directly related to the study at no cost. Depending on how your healthcare expenses is paid for, you may have some personal expenses. The study staff can explain further.

If you spend money to be a part of this study, you may be able to get some or all of it back. You will only be given money back for expenses associated with study activities completed. The study staff will provide you and review more details around how reimbursement will be received.

Using the mobile app may use data from your mobile data plan. You are responsible for any data charges from your mobile provider. To reduce data costs, use secure WiFi whenever possible. For support with the mobile app, please contact your study team.

4. What do I have to do?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you. The study doctor will talk to you about any recommended or required lifestyle restrictions.

- You must follow the study procedures and go to all the study visits. Please inform the study doctor if you will not be able to attend a visit.
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.
- You must report any changes to your well-being, including any side effects, to the study doctor.
- You must tell the study staff about any other medication you are taking or if you have any changes to your medications during the study. Tell the study doctor before you start a new medication.
- You are not allowed to take part in any other research study with an investigational product while you are in this research study.
- You must use and/or return the study drug during the study as instructed by the study doctor and study staff.

The study doctor or a member of the study staff has discussed with you the requirements for participation in this research project. It is important that you are open and honest with the doctor and staff about your health history. You cannot take part in this research project if you do not meet all qualifications.

Sponsor request for confidentiality
The sponsor wants to keep the information in this document confidential. Please share it only if you need to decide whether to join or stay in the study, if you have questions about your rights, or when getting medical care from healthcare professionals.

Lifestyle changes you may need to make

Participating in a clinical study:

- may require you to make lifestyle and medication changes
- could expose you to unknown risks

Below are the lifestyle changes that you may need to make if you participate in this study. Your study doctor will explain the lifestyle and medication changes you need to follow based on your situation.

Here are some things to think about regarding other medications you take and possible lifestyle changes:

Medication and Vitamins

- You may not be able to take your usual medications or supplements, and you may need to make some changes to your daily routine.
- If you decide to take any new medications or supplements while in the study, make sure to talk to your study doctor first.

Meals and Diet

- You may need to avoid food and drinks before certain visits. The study doctor will remind you if this is the case.

Other Lifestyle Restrictions

- You should abstain from heavy exercise for 24 hours before blood draws. You may engage in light activities such as watching television or reading during the study.
- You should not donate blood during the study and for 10 weeks after your last dose of study drug.

5. Other relevant information about the study

Up to 1980 participants will be taking part worldwide in this study. Up to 91 participants will be taking part in this study in Australia.

6. Do I have to take part in this study?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Life Clinical Research.

7. What are the alternatives to participation?

You do not have to take part in this study get treatment for your condition.

There are other ways to manage your condition.

These options might include:

- Different medicines to treat obesity or overweight
- Non-medicine treatments for obesity or overweight
- Choosing not to have any treatment

The study doctor can discuss these options in more detail with you, including potential benefits and risks, before you decide whether or not to take part in this study. You can also discuss the options with your local doctor.

8. What are the possible benefits of taking part?

No matter what treatment you receive as part of the study, you may not receive any medical benefits. This means that your obesity or overweight may not improve or may get worse.

You will be given close attention from the study staff during the time you are involved in the study. You may get information about your health from physical examinations and medical tests done in this study.

If the results of this study are favourable and lead to approval of eloralintide in humans, there may be benefits for people with obesity or overweight without T2D in the future.

Your samples may help with the development of other items, such as products or procedures, that may be worth money to the sponsor. You will not receive any rewards or benefit from this.

There will be no clear benefit to you from your participation in this study.

9. What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below and they may be mild, moderate or severe. If you have any of these side effects or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. **If you have unexpected or troubling symptoms while you are in the study, contact your study doctor and, if you feel it is necessary, seek emergency medical care by calling 000.** Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting, or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Participating in a clinical study may not help you and has potential known and unknown risks. The study doctor will speak to you about all the potential risks to you. Below are the known risks for you to consider if you participate in this study.

Risks for drugs in the study

Below are the known risks for the study drug being tested. You may experience some, all, or none of the side effects listed below.

Eloralintide

109 people have been treated with eloralintide in completed clinical trials. Of these,

- 36 were healthy adult volunteers, and
- 73 were adults with obesity or overweight.

In ongoing trials, 41024 people with obesity or overweight are taking either the study drug or placebo, for example, an injection that does not contain active medicine.

Risks Associated with Eloralintide

Our understanding of the risks of eloralintide may change as we gain more experience. This is what we currently know.

Risks for All Studies

Very Common and Common Side Effects of the Study Drug

Very Common (10 or more out of 100 people)	**Common (1 or more, but less than 10, out of 100 people)**
Less hunger	Headaches
Diarrhea	Stomach pain
Tiredness	Bloating
Nausea	Injection site reaction such as, pain at the injection site, bleeding, bruising, skin rash, itching, swelling, or redness after injection
Constipation	Vomiting
	Feeling unhappy or sad
	Dry mouth
	Indigestion
	Decreased heart rate
	Acid reflux
	Feeling of fullness
	Hair loss

Other Safety Information

Some of these side effects have also been reported with study drug:

Decreased heart rate and blood pressure

- You may experience decreased heart rate below the normal range (less than 60 beats per minute) or slight decrease in blood pressure, or both if you take eloralintide.

Dehydration

- If you experience severe effects like diarrhea, nausea, and vomiting, you may become dehydrated (excess loss of fluids). This could worsen kidney function and lead to fainting or kidney failure.
- You may need to be admitted to the hospital to treat the symptoms. Treatment may include fluids through the blood vessels in your arm.

Allergic reactions

- Allergic reactions can occur causing redness, itching, swelling or pain at the site of the injection.
- Rarely, people who have taken other medicines that work like the study drug have reported serious allergic reactions including potentially life-threatening allergic reactions. This has not been observed in people taking the study drug.

Animal Safety Data

The study drug has been given to animals. The information from animal studies may be useful to you in considering whether to participate in the study because similar effects could be observed in people. Important effects seen in animals are as below:

- decreases in body weight and food consumption
- slower heartbeat, lower blood pressure, or both, and
- pregnant animals that were given study drug and lost too much body weight had babies with less weight and with some birth defects (in rats).

Important Signs and Symptoms

It is important to notify the study doctor right away if you have any of the problems below, because they could indicate a serious problem.

Call the study doctor right away if you have…	**Because it may indicate…**
For All Participants	
• dizziness • feeling faint, or • passing out	decreased heart rate and blood pressure
• thirst • dry mouth • dizziness (especially while standing) • tiredness, weakness • diarrhea • nausea, and • vomiting	dehydration from a lack of fluid intake or fluid loss
• fever, chills, joint pain, muscle pain, skin rash, nausea, dizziness,	allergic reaction

Call the study doctor right away if you have…	Because it may indicate…
headache, throat irritation, and shortness of breath • low blood pressure, wheezing, and difficulty breathing	

Risks for study activities

There might be some risks with the activities in this study. Most of the activities are regular medical procedures, and the risks are the same whether they are done in the study or outside of it. The study staff can answer any questions you have about what will happen in the study and the risks for you.

The following are risks associated with the activities in this study.

Blood Tests	You might feel a quick pinch when the needle goes in, and sometimes a bruise might form. After the procedure, you might feel dizzy or faint.
DXA Scan	A tiny amount of radiation is used that is generally considered safe, especially for a single test.
ECG	You might feel a bit of discomfort when the devices are placed on or removed from your skin. You might have mild skin irritation after the test.
Subcutaneous Injections	You might feel a sting from the needle. After the injection, the area might be sore or have a small bruise, and occasionally, there might be redness or swelling.
Questionnaires	Some people may find that doing the questionnaires is upsetting or embarrassing.
Oral Glucose Tolerance Test (OGTT) – only for participants with prediabetes	You might feel some nausea or dizziness from drinking the sugary liquid.

Risks Related to Using Your Personal Mobile Device

If you use your personal mobile device for this study, there may be certain privacy and security risks.

- If your device is lost, stolen, or used by others without permission, they might see your study data.
- You will need to install a mobile application for the study on your device. This application might use mobile battery and data. This can lead to extra data charges from your service provider.

You will need to follow these steps:

- create a password or code to access the application
- create a strong password to protect your device, and

- enable automatic locking for added security.

If your device is lost or stolen, report it to the study team right away.

Reproductive Risks

The effects of eloralintide on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project.

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All participants are strongly advised to use effective contraception (birth control) during the course of the research project and for 70 days after receiving the last dose of eloralintide (males) or 70 days after receiving the last dose of eloralintide (females). There may be risks of interactions between the eloralintide and certain kinds of birth control. Your study doctor can discuss your specific risks in more detail. The study doctor will review with you whether you may need to use birth control, which methods of birth control are required, or any other restrictions needed while you are in the study.

For female participants: Birth control should be used during the study and for 70 days after receiving the last dose of eloralintide. You should not donate ova/egg for 70 days after receiving the last dose of the eloralintide. If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

For male participants: Birth control should be used during the study and for 70 days after receiving the last dose of eloralintide. You should not father a child or donate sperm during the study and for 70 days after receiving the last dose of eloralintide. You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

DXA Scan

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.05 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal

10. What will happen to my test samples?

Samples from your body will be collected from you during this study. Please see the information below to learn more about how your samples will be used and who will have access to them. The collection of these samples is required for you to participate in this study.

Type	**Purpose**	**Length of time stored**	**Who may use it or see your data**	**Notes**
Blood and Urine	To confirm that you can be in the study and monitor your health.	Until tests are done and confirmed	Only researchers in this study	You may be tested for hepatitis, or other diseases. If blood tests say you have one of these diseases, researchers will contact you. Certain results may be required to be shared to others* based on local law.
Blood	To see how fast your body breaks down the study drug.	Up to 1 year after all participants have finished the study	Only researchers in this study	
Blood	To learn more about obesity or overweight, or how people respond to the study drug.	Up to 7 years after all participants have finished the study	Study researchers and others*	Biomarkers are substances in the body that can tell researchers about a condition. For example, cholesterol in the blood can be a biomarker for heart disease.
Blood	To learn how the study drug works for you or to help find out why people react to drugs differently.	Up to 7 years after all participants have finished the study	Study researchers and others*	DNA (genetic) tells your body how cells should be built and work. Some of these instructions tell your body how to react to drugs.
Blood	To determine if your body produces antibodies against the study drug.	Up to 15 years after all participants have finished the study	Only researchers in this study	Antibodies are substances the body produces to recognize and protect against foreign substances and organisms, such as viruses. Depending on your test results, you may be asked to provide additional samples up to one year after completing the study.

“Others” refers to a business partner or collaborator of the Sponsor who will be required to sign a written agreement to protect your samples and uses the samples as agreed to in this Participant Information Sheet/Consent Form.

Test samples obtained for the purpose of this research project will be transferred to the study central laboratory.

Your samples will be assigned a unique identifying code, but not your name or other individually identifiable information. The study site will share your samples with the Sponsor only after they have been coded, therefore the data is not able to identify you.

All samples will be destroyed based on laboratory procedures, laws, regulations, or international laboratory standards.

11. What if new information arises during this study?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If any important new information is found during this research project that may affect you wanting to continue to be part of this research project, you will be told about it right away.

If you decide to withdraw, you may seek advice from your medical practitioner for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form. Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, your study doctor will explain the reasons and advice for your regular health care to continue.

12. Can I have other treatments during this study?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

13. What if I withdraw from this study?

If you decide to withdraw from the study, please notify a member of the study team before you withdraw. This notice will allow that person or the study supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the study, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

14. Could this study be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons. This could happen if the Sponsor or the study doctor learns new information about the safety of the study drug or the trial, if the study drug is shown not to be effective, if the study drug is shown to work and not need further testing, or for decisions made in the interests of the Sponsor or local regulatory/health authorities. If new information is learned that may affect your decision to stay in the study, the study doctor will tell you promptly.

The study doctor or the Sponsor may also remove you from the study or stop your study drug. This may be because of a bad reaction you experience, or because you did not follow the study plan or the instructions of the study staff. If you are taken off the study, you will no longer receive the study drug. If your study drug is stopped, your study doctor will closely monitor your overall health.

You may be taken out of the study for several reasons. For example, if you have a bad reaction, become pregnant, find out which treatment you are getting before the study ends, or do not follow the study rules. You could also be removed if the sponsor or doctor finds new safety concerns, stops working on the study drug, or closes the study location. If you are removed from the study or choose to not continue, the study doctor will discuss what this means for you.

15. What happens when the research project ends?

Currently, eloralintide will not be provided after the end of the study. If your condition requires further treatment, your study doctor will help you decide what treatment is best for you after the end of the study. Your doctor will speak to you about your health care options. At the time that your participation in this study ends, an extension study testing eloralintide may be available for you to join. Your study doctor will tell you about this if the option becomes available for you.

When the study is over, a summary of the results will be made available. The study doctor can provide more details about when and where you can access the results. You may ask your study doctor to explain the results to you.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. Requirements to join the trial and countries participating can be found on this website.

Information regarding this study can also be found at www.euclinicaltrials.eu/search-for-clinical-trials/ with the study number 2025-523657-34-00.

Study data collected as part of this research study may be published in study reports or medical journals, used for scientific presentations, and may also be shared with, or inspected by, health authorities worldwide. Information that identifies you or that reasonably could be used to identify you will not be included in such publications.

Part 2 How is the research project being conducted?

16. What will happen to information about me?

If you choose to participate in this study sponsored by Eli Lilly and Company (“Lilly”), the study doctor and study staff will collect certain personal information (“PI”) about you. This data

privacy section describes how your PI will be used and with whom it may be shared. It also describes your rights with respect to this information.

Why is your personal information collected and how is it used?

Your personal information is information that identifies you or could reasonably be used to identify you. There are different types of personal information that can be collected as part of your participation in the study.

Categories of personal information that are collected include:

- Basic personal details such as signature, birth year, gender, and education
- Health information such as medical history, prescriptions, health status, test results, and data from connected devices and mobile device information and data entered into the study application.
- Behavioural information such as smoking and eating habits
- Protected characteristics such as racial and ethnic origin
- Biomaterial information such as blood, and urine samples
- Personal contact information such as address, phone, and email address
- Financial information for study participant reimbursement
- Mobile device information and data entered into the study application

Your personal information will be used and shared for the purposes of conducting and overseeing this study as described in this document. Some of the uses include determining if you are eligible for this study, understanding your medical history, assessing your health, and providing medical treatment during the study. The study doctor and study staff will collect personal information about you from your existing health records or directly from you and store it in a study-specific database only accessed by authorized individuals.

How is your personal information protected?

The study doctor and study staff will share information with the sponsor and representatives working on behalf of the sponsor, however they will assign a code number to represent your personal information to protect your identity.

How is your coded personal information used and shared?

The sponsor, its affiliates, and business partners may use this coded data in the following ways:

- As part of this study;
- To meet global regulations and approvals;
- For legal purposes (for example, litigation);
- To publish its findings in study reports or scientific presentations;
- For further medical research projects or development of medical products/devices/diagnostic tests
- For further examination of the safety or efficacy and/or identification of new medical uses of any medical products/devices/diagnostic tests or treatment included in the study;

- For further examination of the disease(s) or condition(s) that are the subject of the study to identify new learnings;
- To analyze how the sponsor can improve its clinical research processes;
- To develop artificial intelligence and/or machine learning tools that can help us learn more about the disease or condition being studied; and
- To analyze the study data using artificial intelligence and/or machine learning tools.

The sponsor may share this coded data for the purposes in this document with its affiliates, business partners, regulatory agencies in countries around the world, and ethics committee(s). Once shared, this data may fall under data protection laws in other countries that may be less protective than data protection laws in the country or region in which you are participating in this study, however, the sponsor will continue to protect your coded data and use the data only for the purposes described in this document.

How long will your information be stored?

Records containing your personal information will be retained at the study site for a period of up to 15 years after the end of the study. In addition, the sponsor will retain the coded data for up to 5 years after marketing of the study drug has completed.

What are your rights related to your personal information collected, used or shared during the study?

You have the right to see and get a copy of your personal information used in the study. Please note however, that while you are participating in the study, your access to your personal information in the study records may be limited to protect the integrity of the study and results. You have the right to withdraw your consent for the collection, use, and disclosure of your personal information for this study at any time. If you decide to withdraw your consent, you cannot continue to participate in the study. Personal information collected prior to your withdrawal of consent must be maintained in the study records due to regulations. To meet regulations, the sponsor, its affiliates, or its business partners may request information about your health status after you withdraw from the study (for example, tracking for an adverse event).

You may also have other legal rights related to your personal information based on where you participate in the study. You may contact the study staff listed in “Further information and who to contact” to understand your rights.

If you are not satisfied with the response or believe the study site or the sponsor is not processing your personal information in accordance with the law, you can file a complaint with the relevant regulatory agency (for example a Data Protection Authority or an Attorney General).
If you are not satisfied with the response or believe the Study Site or Lilly are not processing your PI in accordance with the law, you can file a complaint with the relevant regulatory authority (e.g., a Data Protection Authority such as the Office of the Australian Information Commissioner, or your applicable state-based equivalent.)

17. Complaints and compensation

If the study plan is followed correctly, you follow the directions of the study doctor and staff and you are physically injured as a direct result of a study procedure or drug, you should contact your study doctor as soon as possible for assistance with arranging appropriate

medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

There are two avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this study:

- The pharmaceutical industry has set up a compensation process, with which the Sponsor, Eli Lilly Australia Pty Ltd, of this research project has agreed to comply. Details of the process and conditions are set out in the *Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in a Company-Sponsored Clinical Trial. These guidelines are available for your inspection on the Medicines Australia Website (www.medicinesaustralia.com.au).* In accordance with these Guidelines, the sponsor will determine whether to pay compensation to you, and, if so, how much. A copy of the Guidelines is available to you from the research staff on request.

- You may be able to seek compensation through the courts.

18. Who is organising and funding the study?

This study is being conducted by Eli Lilly and Company, and sponsored in Australia by Eli Lilly Australia Lty Ltd.

Eli Lilly and Company may benefit financially from this study if, for example, the project assists Eli Lilly and Company to obtain approval for a new drug/device.

By taking part in this study you agree that samples of your blood or tissue (or data generated from analysis of these materials) may be provided to Eli Lilly and Company. Eli Lilly and Company may directly or indirectly benefit financially from your samples or from knowledge acquired through analysis of your samples.

You will not benefit financially from your involvement in this study even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to Eli Lilly and Company.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to Eli Lilly and Company, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

Life Clinical Research will receive a payment from Eli Lilly and Company for undertaking this research project.

No member of the research team will receive a personal financial benefit from your involvement in this study (other than their ordinary wages).

19. Who has reviewed this study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by Bellberry Human Research Ethics Committee.

This research project will be carried out according to the *National Statement on Ethical*

Conduct in Human Research 2025 -. This statement has been developed to protect the interests of people who agree to participate in human research studies

20. Further information and who to contact

The person you may need to contact will depend on the nature of your query.
If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in this study (for example, any side effects), you can contact the principal study doctor on 07 3180 8045 or any of the following people:

Clinical contact person

Name	Dr. Cameron Booth
Position	Principal Investigator and Cardiologist
Telephone	3180 8045
Email	cameron@LCR.Health

For matters relating to research project at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Paul Christensen
Position	Clinical Operations Director
Telephone	0417 108 585
Email	Paul@LCR.Health

If you have any questions, concerns or complaints about your rights as a participant in a research project, please contact:

Reviewing HREC approving this research project and HREC Executive Officer details

Reviewing HREC Name	Bellberry Human Research Ethics Committee
HREC Executive Officer	Jerneen Williams
Telephone	0883613222
Email	bellberry@bellberry.com.au

Main Participant Consent Form

Title	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Once Weekly Eloralintide in Adult Participants with Obesity or Overweight, without Type 2 Diabetes (ENLIGHTEN-1)
Short Title	ENLIGHTEN-1
Protocol Number	J3R-MC-YDAG
Project Sponsor	Eli Lilly and Company
Principal Investigator	Dr. Cameron Booth

Consent Agreement

Joining the study is your decision. To agree to take part in this study, please sign and date below. Signing this consent page means that:

I understand that my general physician (GP) may be notified of my participation in this study.

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand all of the information I have been given about this study.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this clinic to release information to **Life Clinical Research** concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions, all of my questions have been answered, and I have had time to think about the study.

I agree to be part of the study as described, and I understand that I can decide to withdraw from the study at any time without affecting my future health care.

I have given my free and informed consent to be part of this research study. I understand that I will be given a signed copy of this document to keep.

I agree to use a mobile device and the required mobile app for this study. The device will be one provided by the sponsor or my personal device. I understand the privacy and security risks of using a device for study purposes, as detailed in this document.

Declaration by Participant Who Have Read the Information

Name of Participant (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

For Participants Unable to Read the Information and Consent Form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*

Name of Witness to the Informed Consent Process (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the study, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor or Senior Researcher‡ (please print) _____

Signature _____ **Date** (dd mmm yyyy) _____

† A senior member of the research team must provide the explanation of, and information concerning, the study.

Note: All parties signing the consent section must date their own signature.